3M ESPE
Dental Products

3M Center
St. Paul, MN 55144-1000
651 733 1110

K111185

3M ESPE

MAY - 5 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter..... 3M Company
3M ESPE Dental Products
3M Center, Bldg. 260-2A-11
St. Paul, MN 55144-1000 USA

Contact person..... Bernardo M. Medellin J.D.
Regulatory Affairs Specialist
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Date Summary was Prepared.....March 31th, 2011

Trade Name.....RelyX™ Luting Plus Automix
Resin Modified Glass Ionomer Cement

Common Name(s)..... Dental Cement, polymer based

Recommended Classification.....Resin Modified Glass Ionomer Cement
(21 CFR 872.3275, Product Code: EMA)

Predicate Devices:
3M™ ESPE™ RelyX™ Luting Plus Cement (K022476)

Description of Device:

3M™ ESPE™ RelyX™ Luting Plus Automix (Lexus-2) is a radiopaque, fluoride-releasing, resin-modified glass ionomer luting cement. It is self-curing with an option for tack light curing of excess cement. RelyX Luting Plus Automix (Lexus-2) consists of a base (Paste A) and catalyst (Paste B) packaged in an automix (dual barrel) syringe. The dual barrel syringe dispenses paste A and Paste B. The cement is available in a white shade.

Indications for Use:

This device is intended for use as a dental cement. RelyX ™ Luting Plus Automix (Lexus-2) is indicated for Luting:

- Luting porcelain fused to metal crowns and bridges to tooth structure, amalgam, composite or glass ionomer core build ups;
- Luting metal inlays, onlays or crowns;
- Luting pre-fabricated and cast post cementation
- Luting orthodontic appliances
- Luting crowns made with all-alumina or all zirconia cores such as Procera® AllCeram

Substantial Equivalence:

Information provided in this 510(k) summary shows that the product is substantially equivalent to 3M ESPE's predicate device, RelyX™ Luting Plus Cement (K022476).

Bench Test Data Comparison with Substantially Equivalent, Currently Marketed Device				
Properties	**Method**	**Lexus 2 Design Specification**	**Lexus2 Ave and**	**RelyX Luting Plus (predicate K022476)**
Flexural strength (FS) (MPa)	ISO 9917-2	≥ 10 MPa	pass	pass
Radio-opacity (mm of Al)	ISO 9917-2	≥1.0mm of Al	pass	pass
Adhesion to dentin (MPa)	3M ESPE internal	≥2 MPa	pass	pass
Adhesion to enamel (MPa)	3M ESPE internal	≥2 MPa	pass	pass
Adhesion to Metal (MPa)	3M ESPE internal	≥2 MPa	pass	pass
Adhesion to Lava™ (MPa) zirconia	3M ESPE internal	≥2 MPa	pass	pass
Adhesion to composites	3M ESPE internal	≥2 MPa	pass	pass
Adhesion to amalgam	3M ESPE internal	≥2MPa	pass	pass
Adhesion to Titanium (MPa)	3M ESPE internal	≥2 MPa	pass	pass
Adhesion to Lithium disilicate (MPa)	3M ESPE internal	≥2 MPa	pass	pass
Fluoride release (µg F/g) at 90 days	3M ESPE internal	≥500	pass	pass
Film thickness (microns)	ISO 9917-2	≤ 25	pass	pass
Work time (s)	3M ESPE internal	≥ 90s	pass	pass
Set time (s)	3M ESPE internal	≤480s	pass	pass

Environmental, health and safety (EHS) risks for RelyX™ Luting Plus Automix were evaluated using a process compliant with ISO14971:2007, *Medical Devices - Application* of *Risk Management to Medical Devices* and with specific procedures and practices outlined by 3M ESPE's Standard Operating Procedures. The conclusion of the risk assessment is that the product RelyX™ Luting Plus Automix is safe for its intended use.

A biocompatibility assessment was developed for this new product using ISO 10993-*1:2009(E) Biological evaluation of medical devices.*Testing included Genotoxicity, cytotoxicity, sensitization, and systemic toxicity. The conclusion of the assessment is that the product RelyX™ Luting Plus Automix is safe for its intended use.

Combined with biocompatibility testing, based on a comparison of intended use and indications for use, contraindications, physical properties, and composition, 3M ESPE concludes that RelyX™ Luting Plus Automix is substantially equivalent to the named predicate device RelyX™ Luting Plus Cement (K022476). No new concerns about safety or effectiveness have been identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

3M ESPE Dental Products
C/O Mr. Bernardo Medellin
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

MAY - 5 2011

Re: K111185
Trade/Device Name: RelyX Luting Plus Automix – Resin Modified Glass Ionomer Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: April 26, 2011
Received: April 27, 2011

Dear Mr. Medellin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: RelyX™ Luting Plus Automix – Resin Modified Glass Ionomer Cement

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111185